

REMARKS

1. Examiner's Interview

The undersigned attorney appreciates the telephonic interview provided by Examiner Tanner on April 1:

- (1) To clarify the Advisory Action, namely whether the prior §103 rejections in view of US 2003/0032859 to *Belson* and U.S. 5,486,127 to *Wolfe* were maintained (with the Examining Attorney confirming that they were maintained); and
- (2) To review the rejections, cited references, and the Applicants' responsive arguments in greater detail. Here it is understood that:
 - The *Belson / Wolfe* §103 rejections are maintained because *Wolfe* is regarded as analogous art, and even if Applicants' arguments in the last Response are correct – e.g., that no artisan would consider incorporating *Wolfe*'s “tabbed ball”-and-socket structure into *Belson* owing to loss of flexibility and difficulty obtaining *Belson*'s vacuum – *Wolfe*'s ball-and-socket arrangement would nonetheless be beneficially introduced into *Belson* because having a ball on one *Belson* segment snap-fit into an adjacent *Belson* segment would better retain the *Belson* segments together, e.g., during withdrawal of the segments from a body;
 - The arguments against the *Danitz / Van Hoose* §103 rejections – which are clarified and amplified below to further reflect discussions during the interview – were found persuasive, particularly insofar as introducing a *Van Hoose* ball-and-socket arrangement into *Danitz* would limit the flexibility and degrees of freedom of *Danitz*, and such a combination would not be contemplated by an ordinary artisan.

2. The Amendments, the Support Therefor, and Basis for Entry

One claim (claim 30) is newly canceled, two new claims (32 and 33) have been added, and claims 1 and 16 have been amended to leave claims 1, 5-12, 15-19, 22, 25-29, and 31-33 in the application. No new matter has been added by the amendments or new claims, wherein:

Claims 1 and 16 are amended to recite the ball-and-socket arrangement shown in Figures 1 and 3, wherein the ball is freely insertable *and removable* within the socket. For example, the FIG. 3 arrangement shows the socket continuously decreasing in diameter, rather than being narrowed at the mouth and widening as it becomes deeper (an arrangement that would cause the ball to “snap-fit” into the socket). Here the ball lacks such a “snap-fit”:

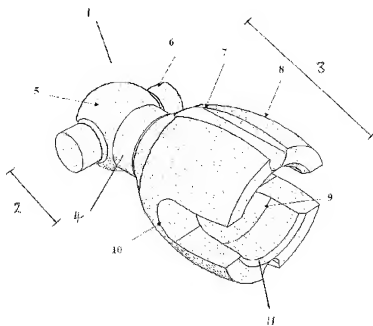


Figure 3

Claim 16 is also amended to incorporate its dependent claim 30.

New claims 32 and 33 find support at page 4 line 29-page 5 line 3 and page 8 lines 18-21.

3. Sections 1-15 of the Office Action: Rejection of Claims 1, 5, 7, 9, 10, 16, 17, 19, 22, 25, and 27-30 under 35 USC §103 in view of US 2003/0032859 to Belson and U.S. 5,486,127 to Wolfe

Belson provides an endoscopic “guide” formed of a freely reconfigurable set of segments which are asserted by the Office Action as having a ball-and-socket mating arrangement (FIG. 7A), and wherein the segments can be rigidly locked in place by applying vacuum along the segments (see, e.g., paragraphs [0023], [0025], [0072], etc.). *Wolfe* describes segments with balls bearing “keys”

(e.g., at 6 and 6B of FIG. 4) which snap-fit into sockets in adjacent segments, with the keys preventing relative rotation between segments (see, e.g., column 1 lines 13-19; column 3 line 66-column 4 line 3; FIG. 2). The Office Action asserts that:

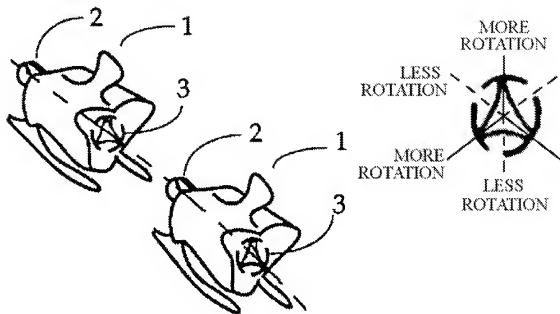
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the balls and sockets of *Belson* with the projections and slots, as taught by *Wolfe*, to control the amount of displacement about the axis of the male and female connectors (column 3, lines 15-25).

(Page 3, also page 6.) From the interview, this “amount of displacement about the axis” is understood to mean the degree by which one segment may “separate from” an adjacent segment, i.e., that incorporating the snap-fit ball-and-socket arrangement of *Wolfe* into *Belson* would help retain the *Belson* segments together, e.g., when *Belson*’s vacuum is released.

Kindly reconsider and withdraw these rejections. Initially, an ordinary artisan who had no knowledge of the claimed invention, but who knew of *Belson* and *Wolfe*, would not contemplate modifying *Belson* to add balls to the segments which are *freely insertable and removable* into sockets in adjacent segments (i.e., which lack the snap-fit arrangement taught by *Wolfe*) as recited in claims 1 and 16. *Wolfe* repeatedly notes the need for a “snap-together” connector (which is necessary for *Wolfe*’s goal of constructing a skeletal model, since otherwise the segments or “bones” will fall apart), and achieves this by sizing the ball larger than the (flexible) socket opening (see column 3 line 66-column 4 line 11, also FIG. 2). Any ordinary artisan who sought to modify *Belson* to prevent the segments from readily separating would simply adopt *Wolfe*’s approach and utilize balls which snap-fit into their sockets, rather than being readily insertable and withdrawable from the sockets, and such an arrangement does not amount to the one recited in claims 1 and 16.

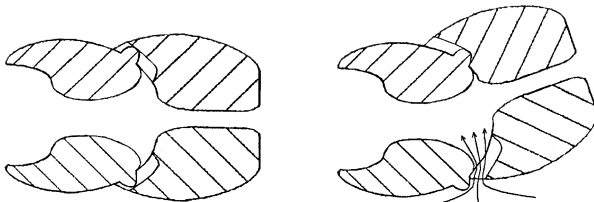
Further, while the Office Action asserts that an artisan would also incorporate *Wolfe*’s projection-bearing balls, and socket walls with projection-receiving slots, into *Belson*, there’s no reason to do so because these features would impart no benefits. More specifically, an artisan would *not* incorporate these features because they would counterproductively limit the pivot angle of each *Belson* segment with respect to adjacent segments along the lengthwise axis of the *Belson* device. Consider that the *Wolfe* projection-and-slot arrangement inhibits pivoting of segments in certain directions: the segment bearing the ball is able to pivot more freely (with respect to the lengthwise

axis of the collective segments) along the slots, since the “stalk” from which the ball protrudes may move within the slot. However, the segment bearing the ball has a limited pivot angle in directions which are not aligned with the slots (in particular, along the dashed lines shown in the illustration below):



Stated simply, the arcuate sectors between the solid lines in the illustration above inhibit pivoting in directions closer to the dashed lines, and allow greater pivoting in directions closer to the solid lines. Given that *Belson* seeks to achieve free pivoting in *all* directions so that the segments can follow complex / tortuous paths, there is no benefit whatsoever to incorporating the projections and slots into *Belson*, and no apparent reason why one would do so.

In addition, as noted in the prior Response, no ordinary artisan would incorporate the *Wolfe* projections and slots into *Belson* because it does not seem possible to add projection-bearing balls to *Belson*, and more particularly slot-bearing sockets, and still achieve the vacuum-tight seal between segments sought by *Belson*. If slots and projections are added, if the segment bearing the projection is to pivot to any appreciable degree with respect to the adjacent socketed segment, at some point one of the slots will be exposed, thereby allowing the entry of air and breaking the vacuum. Consider, for example, the addition of slots and projections to FIGS. 6-7 of *Belson*:



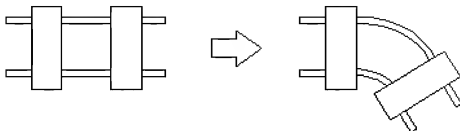
In short, it doesn't seem possible to incorporate the *Wolfe* projections / tabs into *Belson* and still obtain the "vacuum-locking" sought by *Belson*, and since the addition of the projections would thwart the vacuum formation needed to lock *Belson*'s device together (such locking being needed in order to obtain a lockable / usable invention), the addition cannot be obvious. See MPEP 2143.01 (subsection entitled "The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose").

In summary, since the combination of *Wolfe* and *Belson* asserted by the Office Action would provide a ball which snap-fits into an adjacent segment's socket (as in *Wolfe*), rather than a ball which is *freely insertable and removable* into the adjacent socket (as claimed), the claimed invention is unobvious. Further, because the use of projections and slots (as claimed) would unduly limit *Belson*'s flexibility, as well as making it difficult to maintain *Belson*'s desired vacuum, the claimed invention is also unobvious because an ordinary artisan would not contemplate modifying *Belson* to incorporate *Wolfe*'s projections and slots.

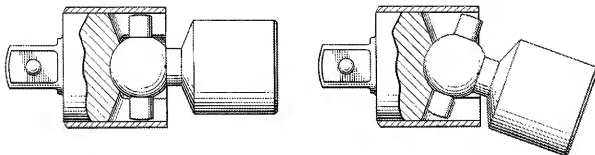
4. Sections 23-32 of the Office Action: Rejection of Claims 16-19, 22, 25, 26, 29, and 31 under 35 USC §102(e) (presumably §103(a) was intended?) in view of US 2004/0236316 to Danitz et al. and US 4,114,401 to Van Hoose

As per the Interview, it is understood that these rejections are withdrawn because incorporating the *Van Hoose* arrangement into *Danitz* would reduce *Danitz*'s flexibility, with no corresponding benefit. In *Danitz et al.*, one segment may pivot at nearly any angle with respect to

an adjacent segment by extending the cable along one side of the device and simultaneously retracting the cable at the other side:



In contrast, *Van Hoose's* arrangement – as illustrated, for example, in FIG. 5 – only allows pivoting of the ball 114 / shank 140 / member 142 by a limited amount, until the shank 140 connected to the ball 114 "bottoms out" in the slot 120:



And further, as with *Wolfe* (discussed above), *Van Hoose* is also limited to pivoting in particular planes/directions, with pivoting being restricted in other directions. Looking to FIGS. 5-6 of *Van Hoose*, consider that *Van Hoose* has greater ability to pivot:

- (1) within the plane of the slot 120 (see FIG. 6 for a better depiction of slot 120), with the ball 114 pivoting clockwise / counterclockwise within the socket 112 in FIG. 5, and with the shank 140 / member 142 "orbiting" the ball 114; and also
- (2) in a perpendicular plane, with the shank 140 / member 142 rotating about the ball 114 out of and into FIG. 5 (or clockwise / counterclockwise about the pin 134 in FIG. 6),

but owing to the protrusion / pin 128's retention within slot 120, the ball 114 / shank 140 / member 142 cannot rotate along other planes. It is therefore clear that the *Van Hoose* arrangement would substantially limit the degrees of freedom by which *Danitz* segments could pivot with respect to

adjacent segments: the ball 114 / shank 140 / member 142 is limited to rotation within the perpendicular planes. Incorporation of such features into *Danitz* would significantly limit *Danitz*'s ability to articulate along a tortuous path, such as that shown in FIG. 1F of *Danitz*.

The end effect is that it can take multiple segments of a *Danitz* / *Van Hoose* combination to achieve the same angle of bend that can be achieved in *Danitz* alone. This limitation in flexibility is seriously problematic when the device is used in sensitive soft tissue (see, e.g., FIGS. 13-14 of *Belson*): the device is supposed to conform to the path of the tissue, rather than requiring the tissue to bend/stretch to accommodate the device (which can cause trauma).

For the foregoing reasons, *Van Hoose* is not capable of the same bending radii, within the same space, as *Danitz* – it cannot in fact “enhance the multiple degrees of freedom” of *Danitz* – and wouldn't be considered for incorporation into *Danitz* for this reason.

As also discussed in the Interview, while the prior Office Action reasoned that one would incorporate the *Van Hoose* projection/slot into *Danitz* because this would “provide a more secure engagement between the male and female parts of the segments that would reduce the wear of the cables of *Danitz*,” this is not in fact so because:

- (1) the *Danitz* segments are in any event effectively “securely engaged” together by the multiple cables;
- (2) no “wear reduction” is avoided because one would still need the same number of cables in a *Danitz*/*Van Hoose* combination as in *Danitz* alone to achieve the same amount of maneuverability (and the tension needed on the cables to effect bends along the length of the device would be the same as in *Danitz* alone, if not greater owing to *Van Hoose*'s resistance to pivoting along angles outside of the plane of the slot 120, and along perpendicular planes); and
- (3) considering modern materials science (and resulting cable strength), and considering that the *Danitz* device is to be urged through passages in soft tissue, the alleged “cable wear” issue is not a problem in any event. (None of the art of record mentions cable wear as a problem.)

In short, no ordinary artisan would truly consider making the asserted *Danitz* / *Van Hoose* combination owing to alleged segment engagement or cable wear considerations.

While not discussed specifically in the Interview, the prior Response also argued that the rejection of claim 25 at Section 28 of the January 12, 2010 Office Action is also legally and factually erroneous. The Office Action contends:

[T]he combination of Danitz et al. and Van Hoose discloses the claimed invention except for segments having lengths that are less than or equal to their diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the segments having lengths that are less than or equal to their diameters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Initially, this is flawed because the stated rationale for the rejection does not adequately reflect the holding of *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980), which stated that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art” (i.e., it’s within the capabilities of an ordinary artisan to tinker with the parameters of known processes to fine-tune the processes). This is not the case here, where no process claims are in issue. Further, as noted in MPEP 2144.04, the Office may only pose an obviousness rejection based on a rationale in a prior court decision “if the facts in [the] prior legal decision are sufficiently similar to those in [the] application under examination”, which is not the case here. The case bears no factual similarities to *Boesch*, wherein the quantities of certain metals in an alloy needed to be optimized to minimize electron vacancies in the alloy. Finally, the erroneous reasoning underlying the rejection is shown by the fact that it doesn't seem possible to adapt the *Van Hoose* arrangement to have the claimed dimensions. Stated simply, if the claimed matter is objectively considered without prejudice and without hindsight, it is seen that the prior art devices cannot be modified to meet the claim with any reasonable expectation of success.

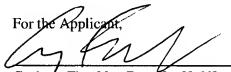
5. New Claims 32-33

New claims 32 and 33 are submitted to be allowable because neither *Wolfe*, *Van Hoose*, nor any other art of record shows or seems to suggest the claimed arrangement.

6. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



Craig A. Fieschko, Reg. No. 39,668
CUSTOMER NO. 25005
DEWITT ROSS & STEVENS S.C.
2 E. Mifflin St., Suite 600
Madison, WI 53703-2865
Telephone: (608) 395-6722
Facsimile: (608) 252-9243
cf@dewittross.com